



SAS:gte 9/3/03 6235-59221
MED-A0102P-US

1635

RECEIVED
PATENT
SEP 09 2003

Attorney Reference Number 6235-59221

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Morishita et al.

Application No. 09/869,475

Filed: June 28, 2001

Confirmation No. 4309

For: GENE THERAPY FOR DIABETIC ISCHEMIC DISEASE

Examiner: Brian A. Whiteman

Art Unit: 1635

Attorney Reference No. 6235-59221

CERTIFICATE OF MAILING

TECH CENTER 1600/2000

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Agent
for Applicant(s)

Date Mailed September 3, 2003

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

TRANSMITTAL LETTER

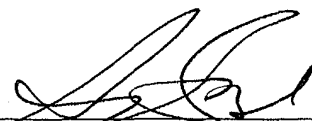
Enclosed for filing in the application referenced above is the following:

Signed Declaration under 37 C.F.R. § 1.132.
On August 13, 2003, Applicants submitted an unsigned Declaration accompanying a response to the Office action dated May 13, 2003. Enclosed is a signed copy of the Declaration.

Please return the enclosed postcard to confirm that the item listed above has been received.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

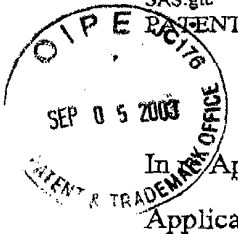
By 
Susan Alpert Siegel, Ph.D.
Registration No. 43,121

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 226-7391
Facsimile: (503) 228-9446

cc: Docketing

SAS:gtc 08/13/03 211841

Attorney Reference Number 6235-59221
Application Number 09/869,475



RECEIVED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SEP 09 2003

In Application of: Morishita

Art Unit: 1635

Application No. 09/869,475

Confirmation No.: 4309

TECH CENTER 1635/2003

Filed: June 28, 2001

CERTIFICATE OF MAILING

September 3, 2003

For: GENE THERAPY FOR DIABETIC ISCHEMIC DISEASE

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service on August 13, 2003 as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Examiner: Brian A. Whiteman

Brian Alpert Siegel
Brian Alpert Siegel, Ph.D.
Agent for Applicant

Date: August 13, 2003

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

1. I, Ryuichi Morishita, am a co-inventor named in the above-referenced patent application.

2. I have read and understand the above-referenced patent application, including the pending claims, and the Office action dated May 13, 2003. Claims 1-12 and 15-20 are rejected as being obvious over Gene Therapy of Osaka University, English translation from the Japan Financial Newspaper, Local News Section (December 14, 1998). This article was published less than one year before the priority application, Japanese Patent Application No. 11/309984, was filed.

3. The article published in the Japan Financial Newspaper is a report of my own work. I worked as an Assistant Professor in the Division of Gene Therapy Science at Osaka University Medical School at the time the article was written, and at the time the invention disclosed in the above-referenced application was made.

SAS:gte 08/13/03 211841
PATENTAttorney Reference Number 6235-59221
Application Number 09/869,475

4. As described in the article, arteriosclerosis obliterans caused by diabetes mellitus is a very serious disease. In the worst case, patients must undergo drastic therapies such as limb amputation. I and my co-inventor, Toshio Ogihara, established a method of treatment of this disease that does not require that a limb be amputated. This work was performed in the Division of Gene Therapy Science at Osaka University. Due to the important clinical implications of this work, we decided to proceed with a clinical trial so that patients could immediately receive the benefit of this important therapy. To initiate a clinical trial in Japan it is required to obtain approval from the Institutional Review Board (IRB) at Osaka University, and then to obtain approval from the Japanese Health Authority. The article in the Japan Financial News reports that our request for approval from the Institutional Review Board (IRB) at Osaka University was filed. Clearly, as this is a report of my own work, my invention was conceived prior to the publication of the article in the Japan Financial Newspaper.

5. I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

*Ryuichi Morishita**2003/08/26*

Ryuichi Morishita, M.D., Ph.D.

Date